

Senate Bill 253 -- Stem Cell Research

Dear Colleagues:

On September 22, 2002, Governor Davis signed Senate Bill 253 (Ortiz) which affirms state policy allowing human stem cell research. The legislation is pasted below and can be found at:

<http://www.leginfo.ca.gov/pub/bill/sen/sb_0251-0300/sb_253_bill_20020830_enrolled.pdf>

What SB 253 does:

SB 253 affirms the policy of the state of California that allows research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells. In addition to affirming state policy, the bill imposes the requirement that human stem cell research be reviewed by an approved institutional review board, and directs health care providers to inform patients undergoing fertility treatments of the options for disposition of human embryos

What SB 253 says:

Section 1

In Section 1, the bill sets forth the justifications for supporting human stem cell research:

- The economic and psychological burden of crippling degenerative diseases;
- The health care costs of these conditions for both the sufferer and society; and
- The immense promise of new therapies to treat these debilitating diseases.

The bill further notes California's preeminent position in biomedical research and the anticipated gains to California's economy of state support of human stem cell research. Finally, the bill states that open scientific inquiry and publicly funded research will be essential to realizing the promise of stem cell research and to maintain California's worldwide leadership in biomedicine and biotechnology.

Section 2

Section 2 adds sections 125115-125117 to the California Health & Safety Code.

Section 125115 provides that stem cell research shall be permitted in California and shall be reviewed by an "approved institutional review board."

Section 125116 requires health care providers to inform patients undergoing fertility treatments of the options for disposition of human embryos and shall obtain written consent for embryo donation to research.

Section 125117 details restrictions on the purchase or sale of embryonic or cadaveric fetal tissue for research.

What SB 253 means for UC:

Institutional Review Boards

Although the bill requires stem cell research to be reviewed by an approved institutional review board, it does not define „approved institutional review board and provides no guidance on: criteria for human stem cell research review, IRB composition for human stem cell research review, or issues to be considered in human stem cell research review. However Section 1(g) states that Stem cell research, including the use of embryonic stem cells for medical research, raises significant ethical and policy concerns, and, while not unique, the ethical and policy concerns associated with stem cell research must be carefully considered. The IRB therefore will likely review the ethical and policy concerns of stem cell research.

The provision requiring IRB review is based on the recommendation of the California Advisory Committee on Human Cloning, a panel established to review issues on cloning following the 1997 federal ban on reproductive cloning. The California Advisory Committee included medical, legal, and bioethics experts, a number of whom are UC faculty, and relied in its deliberations on a report of the 1994 NIH Human Embryo Research Panel. The NIH panel recommended that federal funding of embryo research be allowed

under certain conditions and that those conditions be demonstrated to an IRB established in compliance with federal regulations.

It should be noted that the 1994 NIH panel recommendation that human stem cell research be reviewed by an IRB does not harmonize with OHRP,s recent guidance that human stem cell research is not human subject research and does not require IRB review unless the identity of the donor can be determined by the investigator. See OHRP Guidance for Investigators and IRBs Regarding Research Involving Human Embryonic Stem Cells <<http://ohrp.osophs.dhhs.gov/references/HESCGuidance.pdf>>.

It is clear from the bill,s language and its legislative history that human stem cell research conducted in California must now be reviewed by an IRB. A database search reveals that there are approximately 35 human stem cell research studies under way at UC campuses or labs. The Office of Research at UCOP will be working on creating a framework for IRB review.

Research Funding

SB 253 makes no mention of funding human stem cell research except for the cite referenced above concerning the importance of publicly funded support for such research.

SB 253 and Federal Law Governing Human Stem Cell Research

Research on human embryonic stem cells may be conducted with federal funding so long as the cell lines meet the President,s criteria announced on August 9, 2001 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>). Research on human embryonic stem cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal support.

SB 253 does not conflict with current federal policy; it merely affirms that the state of California permits stem cell research.

~Rebecca Landes

BILL NUMBER: SB 253 ENROLLED
BILL TEXT

PASSED THE SENATE AUGUST 30, 2002
PASSED THE ASSEMBLY AUGUST 26, 2002
AMENDED IN ASSEMBLY AUGUST 23, 2002
AMENDED IN ASSEMBLY AUGUST 15, 2002
AMENDED IN ASSEMBLY AUGUST 12, 2002
AMENDED IN ASSEMBLY JULY 17, 2001
AMENDED IN ASSEMBLY JULY 5, 2001

INTRODUCED BY Senator Ortiz
(Principal coauthor: Assembly Member Wayne)

FEBRUARY 15, 2001

An act to add Article 5 (commencing with Section 125115) to Chapter 1 of Part 5 of Division 106 of the Health and Safety Code, relating to medical research.

LEGISLATIVE COUNSEL'S DIGEST

SB 253, Ortiz. Stem cells: human tissue: research.

Under existing law, it is unlawful for any person to knowingly acquire, receive, sell, promote the transfer of, or otherwise transfer any human organ, for purposes of transplantation, for valuable consideration.

Under existing law, human tissue may be removed in certain circumstances from human remains for the use of the tissue by authorized donees, including, but not limited to, physicians, hospitals, and educational institutions, for transplant, therapeutic, or scientific purposes.

This bill would declare that the policy of the state shall be that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted, as specified. This bill would require a health care provider delivering fertility treatment to provide his or her patient with specified information. The bill would authorize a donation of a human embryo pursuant to specific requirements and would prohibit the purchase or sale of embryonic or cadaveric fetal tissue for research purposes.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. The Legislature finds and declares all of the following:

(a) An estimated 128 million Americans suffer from the crippling economic and psychological burden of chronic, degenerative, and acute diseases, including diabetes, Parkinson's disease, cancer, and Alzheimer's disease.

(b) The costs of treatment and lost productivity of chronic, degenerative, and acute diseases in the United States constitutes hundreds of billions of dollars every year. Estimates of the economic costs of these diseases does not account for the extreme human loss and suffering associated with these conditions.

(c) Stem cell research offers immense promise for developing new medical therapies for these debilitating diseases and a critical means to explore fundamental questions of biology. Stem cell research could lead to unprecedented treatments and potential cures for diabetes, Alzheimer's disease, cancer, and other diseases.

(d) The United States and California have historically been a haven for open scientific inquiry and technological innovation and this environment, coupled with the commitment of public and private resources, has made the United States the preeminent world leader in biomedicine and biotechnology.

(e) California's biomedical industry is a critical component of the state's economy that provides employment in over 2,500 companies to over 225,000 Californians, pays \$12.8 billion in wages and salaries, invests more than \$2.1 billion in research, and reports nearly \$7.8 billion in worldwide revenue, and would be significantly diminished by limitations imposed on stem cell research.

(f) Open scientific inquiry and publicly funded research will be essential to realizing the promise of stem cell research and to maintain California's worldwide leadership in biomedicine and biotechnology. Publicly funded stem cell research, conducted under

established standards of open scientific exchange, peer review, and public oversight, offers the most efficient and responsible means of fulfilling the promise of stem cells to provide regenerative medical therapies.

(g) Stem cell research, including the use of embryonic stem cells for medical research, raises significant ethical and policy concerns, and, while not unique, the ethical and policy concerns associated with stem cell research must be carefully considered.

(h) Public policy on stem cell research must balance ethical and medical considerations. The policy must be based on an understanding of the science associated with stem cell research and grounded on a thorough consideration of the ethical concerns regarding this research. Public policy on stem cell research must be carefully crafted to ensure that researchers have the tools necessary to fulfill the promise of stem cell research.

SEC. 2. Article 5 (commencing with Section 125115) is added to Chapter 1 of Part 5 of Division 106 of the Health and Safety Code, to read:

Article 5. Stem Cell Research

125115. The policy of the State of California shall be as follows:

(a) That research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted and that full consideration of the ethical and medical implications of this research be given.

(b) That research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells, including somatic cell nuclear transplantation, shall be reviewed by an approved institutional review board.

125116. (a) A physician, surgeon, or other health care provider delivering fertility treatment shall provide his or her patient with timely, relevant, and appropriate information to allow the individual to make an informed and voluntary choice regarding the disposition of any human embryos remaining following the fertility treatment.

(b) Any individual to whom information is provided pursuant to subdivision (a) shall be presented with the option of storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research.

(c) Any individual who elects to donate embryos remaining after fertility treatments for research shall provide written consent.

125117. (a) A person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter.

(b) For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.

(c) Embryonic or cadaveric fetal tissue may be donated for research purposes pursuant to this chapter.

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